

Comparison of oxygenation and ventilation with a novel nasal mask vs. standard of care during colonoscopy: a prospective randomized trial

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1. Background

Colonoscopy has become an essential part of the patient management, especially in the field of colorectal cancer prevention.¹ About 15 million colonoscopies were done in the United States in 2012.² Data from United States and European countries suggest that the majority of investigations are performed with the aid of sedation.³⁻⁵ Since sedation can cause significant respiratory depression, resulting in hypoxia, especially in obese and elder populations who are more likely to undergo colonoscopy,⁶⁻⁸ usually oxygen is provided to patients via a nasal cannula to minimize the risk of hypoxia.⁶

Nasal continuous positive airway pressure (nCPAP) has been shown to effectively relieve upper airway obstruction in patients with OSA as it creates a pneumatic stent in the hypopharynx that reduces obstruction and allows for continuous oxygenation.⁹ Nasal ventilation was also proven to be more effective than combined oral–nasal ventilation during induction of general anesthesia in adult subjects.¹⁰ However, it is not clear if nasal mask can be used safely for oxygenation and ventilation in patients undergoing colonoscopy.

The SuperNO₂VA™ device is a new commercially available nasal mask that provides both nasal CPAP and nasal mask ventilation. (Fig. 1) In 2016, Hagberg, et al. in a pilot study demonstrated safety and efficacy with the use of the SuperNO₂VA™ device for nasal mask ventilation (NMV) in anesthetized and paralyzed patients. The objective of this study is to compare the efficacy of oxygenation and ventilation during colonoscopy using the novel nasal mask, SuperNO₂VA™, and standard care with nasal cannula.



Figure 1. SuperNOVA, a new nasal mask produced by the company of Revolutionary Medical Devices of USA. This picture is taken from Revolutionary Medical Devices, USA company website: <http://www.rmdevices.com/products/supernova>.

2. Specific Aims

To randomly and prospectively evaluate the oxygenation and ventilation using SuperNO₂VA™ (a novel nasal mask) vs. standard care (nasal cannula) during colonoscopy.

Hypothesis: SuperNOVA™ is more effective than standard care with a nasal cannula at maintaining oxygenation and ventilation during colonoscopy.

Primary outcome: Time to the first intervention (the time period between the beginning of propofol bolus and/or start of propofol infusion to the time of initiation of the first intervention for airway management).

Secondary outcome:

1. The number of interventions including chin up and/or jaw thrust, oral and/or nasal airway insertion, mask ventilation, intubation with ETT or LMA insertion
2. AUC of interventions
3. O₂ saturation (mean, mode, medium, lowest reading, incidence of reading below 90%, AUC of Sat below 90%)
4. Tidal volume (VT), respiratory rate (RR), minute ventilation (MV)

3. Study Procedures

After IRB approval, this study will be registered on www.clinicaltrials.gov. Before the colonoscopy, demographic data will be collected and physical examination will be obtained from the medical record.

Study protocol: Patients will be randomized to one of two groups using a random number table. Group A: Standard care with a nasal cannula. Group B: SuperNOVA™

In group A, the anesthesia provider will supply oxygen via nasal cannula at desired oxygen flow rates as per routine practice at Vanderbilt University Medical Center (VUMC). In group B, the anesthesia provider will attach the SuperNO₂VA™'s circuit port to the anesthesia machine, turn the oxygen flow rate to 10 L/min, and set the APL valve to 10cmH₂O.

Sedation will be provided by the anesthesia care team and all the drug doses will be recorded. The depth of sedation will be controlled by and monitored by the anesthesia care team. The vital signs will be continuously monitored including SpO₂, NBP, ETCO₂, ECG. VT, RR, MV will be recorded with Padset shown in Fig. 2.¹¹



Figure 2. PadSet placement: A non-invasive Respiratory Volume Monitor (RVM, ExSpiron, Respiratory Motion, Inc.) that provides continuous, realtime, non-invasive measurements of tidal volume (TV), respiratory rate (RR) and minute ventilation (MV). Figure shows standard electrode placement. The PadSet electrode pads are placed on the sternal notch and xiphoid. The third pad is placed along the right mid-axillary line at the level of the xiphoid.¹¹

SuperNOVA Satellite Set

VUMC only has anesthesia machines in 3/8 (37.5%) of their GI rooms.

In order for the SuperNOVA nasal mask to function as intended, it requires a continuous pressure to be generated. To generate this pressure requires a continuous source of fresh oxygen, an adjustable pressure limiting (APL) valve to set and adjust the pressure, and a reservoir bag for the patient to breathe in and out of. Both anesthesia machines and hyperinflation bags consist of tubing that attaches to fresh oxygen, an APL valve, and a reservoir bag. However, the majority of GI procedure rooms do not have anesthesia machines, therefore in order for the SuperNOVA to function as intended it requires a hyperinflation bag to generate a continuous pressure. The study sponsor is providing this additional equipment to be used with the SuperNOVA Mask as needed.

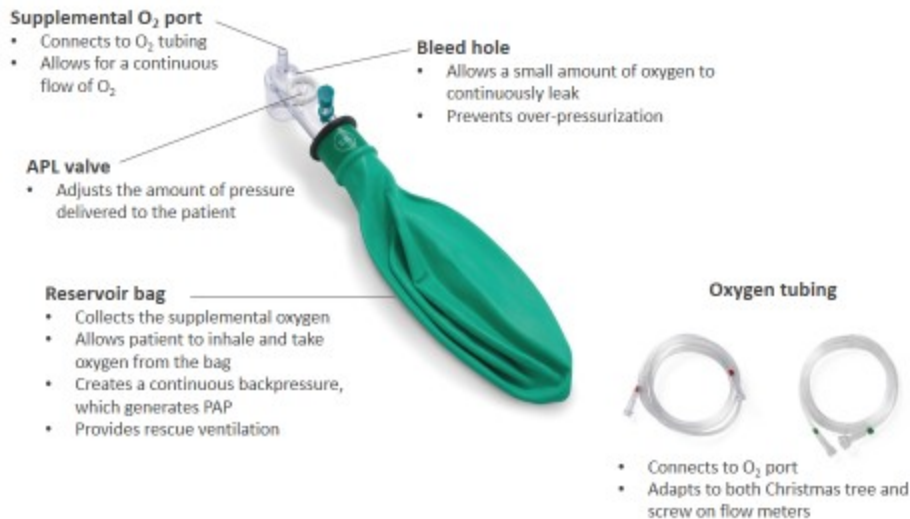
Clinical Benefits of the SuperNO₂VA™ Satellite Set

SuperNO₂VA™ Device + Hyperinflation Bag

- Can be used anywhere a supplemental oxygen source exists (ie: all patient areas, O₂ transport tank, GI suite, PACU, etc.)
- Delivers an FiO₂ of 100%
- Effective for pre-oxygenation during general anesthesia and sedation
- Simple, effective, and disposable continuous positive airway pressure solution
- Improves workflow by relieving upper airway obstruction throughout the peri-operative period
- A rescue ventilation device



Features of the hyperinflation bag



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Once the procedure is over, the patient will be transported to recovery area and vital signs will be continuously recorded until discharge from PACU.

4. Inclusion/Exclusion Criteria

Inclusion criteria: Patients 18 years or older, BMI of 30~50, ASA 1~3, scheduled for colonoscopy with sedation at VUMC.

Exclusion criteria:

- 1) Untreated ischemic heart disease
- 2) Acute and chronic respiratory disorders, including COPD and asthma
- 3) Emergent procedures
- 4) Planned use of an invasive airway (ie: supra-glottic device, LMA, etc)
- 5) Pregnant women
- 6) Nasal or oral disease resulting in difficulty of either nasal breathing or mouth breathing
- 7) Patient refusal

5. Risks

Although nasal mask has long been used clinically, the SuperNOVA™ is a new nasal mask. Hagberg et al performed an observational prospective descriptive study using the SuperNOVA™. It showed that the SuperNOVA™ provided good oxygenation and successful ventilation in 29 of 30 patients with an overall success rate of 97%. It is unlikely that SuperNOVA™ will worsen desaturation or hypoventilation. However, due to applying positive pressure, it could cause gastric insufflation. We will control peak inspiratory airway pressure (PIP) < 20 cm H₂O to prevent gastric insufflation, as normal esophageal sphincter opening pressure is about 20 to 25 cm H₂O.¹² Also, skin irritation during positive pressure application may occur. However, as the positive pressure will be less than 20cm of H₂O and the procedures are generally short, often less than 10 min, skin irritation should be minor¹³

6. Reporting of Adverse Events or Unanticipated Problems Involving Risk to Participants or others

Information regarding adverse events (AE) is to be obtained and documented by the anesthesia attending and/or the investigator performing the data collection and by questioning or examining the patient. All new complaints and symptoms (i.e., those not existing prior to signing of informed consent) will be recorded on the AE CRF. All AEs will be characterized in terms of their start and stop dates, start and stop times, intensity, action taken, relationship to research study, subject outcome and whether or not the AE led to an SAE.

7. Statistical Considerations

We will choose the time to the first intervention for airway management as our primary outcome. Based on our clinical experience, the time to first intervention for airway management is roughly 5 min, we assume that nasal mask prolongs it to 6 min (increasing by 20%, 6/5) with SD +/- 2.2 min, the sample size is 152 and 76 on each arm which allow us to detect the difference between the routine vs. intervention groups with power of 0.8 and type I error rate of 5%. We rounded up to 160 patients.

8. Privacy/Confidentiality Issues

Measures will be taken to prevent lapses in confidentiality from occurring. Only KSP will have access to identified information. Exported and extrapolated data will be stored on a password protected Vanderbilt computer that only KSP can access.

9. Follow-up and Record Retention

All records will be kept through the Dr. Jiang's office. All research tests will be performed under a code that protects the identity of the participants. Records of experimental procedures will be kept at least 6 years following publication of the study results. At that time, the research data that has not been put in the research record will be destroyed.

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